Dr. Harold E Braustein
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Industrial Profile

Cost-conscious and analytical with success optimizing quality, quality assurance, regulation and production processes in fast-paced manufacturing environments.

Areas of Expertise

Quality Assurance- Regulatory- Lean Manufacturing- Just-in-TIME(JIT)- Cost reduction &avoidance- ISO- CE Mark- FDA- GMP- GDP- MDSAP-Supply Chain Management- Statutory audits- Consultancy- Evaluation of deviations- Math, analytical and reasoning skills- V& V Eng.- Professional skepticism- Able to quickly develop a working knowledge of a business and its operations- Life science R&D and Industrial expertise: chemistry, organic, analytical, biology, biochemistry, pharmacology, engineering, biotechnology, drug delivery, Pharma.

EXPERIENCE

Jerusalem, IL

CONSULTANT MEDICAL DEVICES REGULATION
03/2007– present

- In conjunction with Global Co.'s Marketing and Business Manager, develop and support the relevant specific marketing to support business growth
- Develop and evolve the relevant marketing package and tools in collaboration with the Global Operational Marketing Team
- Support the sales, marketing, business development and account activities including sales visits, events/seminars,
- To monitor market trends and track competitors' products to help improving the efficiency of the global business growth strategy
- Actively participate in relevant scheme owner committees or working groups to ensure SGS maintains influence and exposure in the area
- Develop an intimate knowledge of the competition by constantly overseeing competitive activities
- To have overall responsibility for the successful management of the MDR ensuring the global operation is efficient and meets the expectations of internal customers (affiliates), external clients, scheme owners and accreditation bodies

Jerusalem, IL

MEDICAL DEVICES TECHNICAL SPECIALIST
05/2007

- Provide advice and support to product specialists and scheme managers on certifications in area of expertise that may have a regulatory challenge
- Provide "Technical Sales/Networking" support to the commercial team and promote NBs
- Deliver technical reviews and certification scheme management in support of CE marking
- Participate in client meetings to facilitate CE marking processes
- Provide Medical Device expertise leadership and mentoring in areas of competence to medical devices personnel
- A team player good at relationship building internally and externally
- Provide in-house and external training for orthopaedical & non-active dental medical devices

Jerusalem, IL

COMPLAINT ANALYST / MEDICAL DEVICES VIGILANCE/ QMS (9001,13485, CE, 14001,18001), MDSAP AUDITOR
03/2012

- Issues closing letters to affiliates when product analysis has been performed
- Participate on project teams to improve department processes
- Responsible for communicating business related issues or opportunities to next management level
- Maintains knowledge of Co.'s Webster products and their use
- Educates field sales force and affiliates in utilization of complaints department for reporting of field complaints
- Documents all information according to Co.'s Webster policy and EMEA regulatory standards
- Responsible for ensuring personal and company compliance with all local and company regulations, policies and procedures

2019 to date

CERTIFIED AUDITOR
TUV North- Germany
ITC Zlin, Czech Republic
Certified Clinical Investigator, DC

2013 to date

CERTIFIED AUDITOR
IQC- Institute of Quality Control –Petach Tikva

EXTERNAL AUDITOR,
ITC Zlin, Czech Republic- Freelancer-CE Marking/ ISO 13485 Certification

CLIENT TAILOR MADE AUDITS

Dr. Harold Braustein, Lead certified auditor- Israel, EU, US

Challenged with increasing product quality, improving process flow, and reducing costs while improving Quality assurance and regulatory manufacture issues. Performed hundreds of audits of MDSAP/ CE/ QMS in several companies, hospitals, medical laboratories and medical Clinique's in Israel and abroad

Selected contributions:

- Challenged in MDR, MDSAP, 9001, ISO14001, ISO13485, OSHAS 18001 and CE. Certified auditor Environmental and medical
devices audits to different companies in Israel and abroad.
- Performed tests of internal controls to ensure effectiveness. Created and implemented efficiency enhancements to generate more than 12% improvement through associated costs reduction.
- Prepared management reports on audit findings regarding the state of the company's record keeping quality systems.
- Provided constructive recommendations for improvements gaining till 7% increase in productivity and quality.

2007 to date

External Auditor and consultancy provider

QA&RA, R&D, Scientific projects management Independent Consultant

Selected contributions:

- Implement Just-in-time (JIT) strategy to optimize through output and lower warehouse costs as much as 19%
- Redesign QMS within floor layout, achieving 10% improvement in overall productivity while reducing required manpower by 5%.
- Adhered to ethical standards in working with clients with whom there has been no previous relationships with owner or manager.
- When requested by a regulatory agency to perform an audit, reported any evidence to support concerns or suspicions of impropriety.
- Evaluated controls and procedural standards at client site.
- Preparation of company quality management file for ISO9001, environmental and medical devices
- Managed over 10 Laboratories at Teva, Du Pont, Sigma Aldrich, Standard Israeli Institute, System Advanced Laboratories Ltd., Start Ups and others under regulation of CE, ISO17025, MOH, FDA, GMP.
- Industrial Experience---30 years—Companies: Quest Diagnostics Ltd., Fl, Teva, ISI (Israeli Standards Institute), Sigma-Aldrich, Life Science Start Up Companies, Medical Cannabis, emphasis QC/QA&RA, organic synthesis/ analytical chemistry, R&D, Validations, Microbiology, drug delivery, RA, IVD, small molecules diagnosis kits

EDUCATION AND CREDENTIALS

2009 – 2010 Post-Doctoral Studies on POC-electrochemical biosensors-Medical Biochemistry, Drug Delivery and Electrochemistry MIT Collaboration with Boston Scientific Ltd., Boston MA

2008 – 2009 Post-Doctoral Studies-Drug Delivery- "Intelligent water" for skin diseases-Medical Biochemistry, Drug Delivery and Electrochemistry, Hadassah Ein Kerem Pharmacology Institute, The Hebrew University of Jerusalem

2007 - 2009 Post-Doctoral Studies-**Diabetes Type II Treatment** by OM clusters-Medical Biochemistry and Molecular Biology, Silverman Life Science Institute, The Hebrew University of Jerusalem

2002 - 2007 Ph.D. - Chemical Engineering, Sp.: Wastewater Provided by organic synthesis plants purification by laser effect, Gh. Asachi University-Iasi Romania

1986 - 1992 M.Sc.**- Chemical Engineer- Colors for synthetic and optical sieves**, "Gherghe Asachi" University- Iasi Romania.

2013- date QA Certifications:9001, 13485, 14001, 18001, MDR, CE Mark

2019 FDA Clinical Investigator certification, Washington D.C.

SKILLS

- Good computer skills with knowledge of Microsoft Office
- Strong verbal and written communication skills, including the ability to make effective and persuasive presentations
- Demonstrated ability to work effectively in a highly charged, fluid environment
- Very detail-oriented, well-organized, and driven to meet deadlines and program goals
- "Combination" Medical Device/Pharma/Disposables Products
- A self-starter with the ability to work as a Project Leader managing projects and allocation of resources to those projects
- Demonstrated ability to independently manage multiple projects
- Disposable Medical Devices
- Demonstrated working knowledge of scientific principles
- 30 years' related experience industry, academic, start-up, self-employed